

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton Dickinson GmbH Tullastrasse 8 – 12 69126 Heidelberg, Germany		
Manufacturer SRN:	DE-MF-000018170		
Authorised Representative:	Not applicable		
Authorised Representative SRN:	Not applicable		
Product:	Catalog Number	Product Trade Name	
	255084	BD Baird-Parker Agar	
	254007	BD Columbia CNA Agar with 5% Sheep Blood	
	254072		
	255506	BD DNase Test Agar	
	254094	BD Gardnerella Selective Agar with 5% Human Blood	
	254050	BD Group A Selective Strep Agar with 5% Sheep Blood (BD ssA™)	
	255011	BD LBS Agar	
	254520	BD Middlebrook 7H10 Agar	
	254521		
	254444	BD Neomycin Agar with 5% Sheep Blood	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	255084	BD Baird-Parker Agar	038290ECBCCOAIRZ
	254007	BD Columbia CNA Agar with 5% Sheep Blood	038290DSABLDGHZW
	254072		
	255506	BD DNase Test Agar	038290EGIJAAVFYJ
	254094	BD Gardnerella Selective Agar with 5% Human Blood	038290DXDSMKDDCH
	254050	BD Group A Selective Strep Agar with 5% Sheep Blood (BD ssA™)	038290DVSKIYJCGL
	255011	BD LBS Agar	038290DYPQKIWPJZ

	254520	BD Middlebrook 7H10 Agar	038290DYOJDDTYE6
	254521		
	254444	BD Neomycin Agar with 5% Sheep Blood	038290DYISSBRLGS
Risk Class and Rule :		Class A, Rule 5(a)	
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	255084	BD Baird-Parker Agar	BD Baird-Parker Agar is a moderately selective and differential medium for the isolation and enumeration of <i>Staphylococcus aureus</i> in foods, environmental, and clinical specimens.
	254007	BD Columbia CNA Agar with 5% Sheep Blood	BD Columbia CNA Agar with 5% Sheep Blood is a selective medium used for the isolation of Gram-positive bacteria (especially staphylococci and streptococci) from clinical specimens.
	254072		
	255506	BD DNase Test Agar	BD DNase Test Agar is used for differentiating microorganisms based on deoxyribonuclease (DNase) activity. In clinical microbiology, this medium is not used as an isolation medium on which specimens are streaked directly but requires the use of pure cultures such as those previously isolated from clinical specimens.
	254094	BD Gardnerella Selective Agar with 5% Human Blood	BD Gardnerella Selective Agar with 5% Human Blood is a partially selective and differential medium for the isolation of <i>Gardnerella vaginalis</i> from clinical specimens.
	254050	BD Group A Selective Strep Agar with 5% Sheep Blood (BD ssA™)	BD Group A Selective Strep Agar with 5% Sheep Blood (BD ssA™) is a selective medium for use in the isolation and presumptive identification of group A streptococci from throat cultures and other clinical specimens.
	255011	BD LBS Agar	BD LBS Agar (also known as Rogosa Agar) is a semi defined, partially selective medium for the isolation and enumeration of lactobacilli from intestinal, vaginal, and dental flora, especially for identification of disorders of the normal flora.
	254520		

	254521	BD Middlebrook 7H10 Agar	BD Middlebrook 7H10 Agar is used for the isolation and cultivation of mycobacteria.
	254444	BD Neomycin Agar with 5% Sheep Blood	BD Neomycin Agar with 5% Sheep Blood is a selective medium used for the isolation of group A and B streptococci from clinical specimens.
Notified Body:	Not applicable, devices self-certified		
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s): <ul style="list-style-type: none">Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.			

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input checked="" type="checkbox"/> ANNEX I & II+III	N/A

Common Specifications (CS):


Number:	Title:	Full or Partial Application:

Common specifications have not been issued for these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
255084	BD Baird-Parker Agar	Class A
254007	BD Columbia CNA Agar with 5% Sheep Blood	Class A
254072	BD Columbia CNA Agar with 5% Sheep Blood	Class A
255506	BD DNase Test Agar	Class A
254094	BD Gardnerella Selective Agar 5% Human Blood	Class A
254050	BD Group A Selective Strep Agar with 5% Sheep Blood (BD ssA™)	Class A

255011	BD LBS Agar	Class A
254520	BD Middlebrook 7H10 Agar	Class A
254521	BD Middlebrook 7H10 Agar	Class A
254444	BD Neomycin Agar with 5% Sheep Blood	Class A

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton Dickinson GmbH
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	<p>DocuSigned by:</p> <p><i>Anne Zavertnik</i></p> <p> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:31:56 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</p>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change, removed not available from common specifications table and formatting changes